USSN 09/975,350
Art Unit: 1618

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of the Claims

1. (currently amended) A non-aqueous particle-forming composition comprising a modafinil compound and at least one surfactant, ~~wherein~~characterized in that the composition ~~contacting said non-aqueous particle-forming composition with an aqueous medium~~ spontaneously forms an aqueous, liquid, homogeneous, stable[[,]] composition of non-crystalline particles ~~comprising the modafinil compound~~ when contacted with an aqueous medium.

2. (currently amended) ~~The~~A composition comprising a surfactant and non-crystalline particles comprising a modafinil compound, wherein the composition is aqueous, liquid, homogeneous, stable ~~composition of claim 1~~, translucent, and optically isotropic.

3. (currently amended) The composition of ~~claims~~claim 1 ~~or 2~~, wherein the modafinil compound is modafinil.

4. (currently amended) The composition of ~~claims~~claim 1 ~~or 2~~, wherein the composition is pharmaceutically acceptable.

5. canceled.

6. canceled.

7. canceled.

8. (currently amended) The composition of ~~claims~~claim 1 ~~or 2~~, wherein the surfactant or surfactants comprise from about 0.5% to about 50% (w/w) of the non-aqueous particle-forming composition.

9. (previously presented) The composition of claim 8, wherein the surfactant or

surfactants comprise from about 1% to about 20% (w/w) of the non-aqueous particle-forming composition.

10. (currently amended) The composition of ~~claims~~claim 1 ~~or 2~~, wherein the surfactant or surfactants is a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of polyethylene glycol, a medium chain monoglyceride, a medium chain fatty acid ester, d-α-tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, or an ethoxylated hydroxystearic acid.

11. (currently amended) The composition of claim 10, comprising a first surfactant and a second surfactant.

12. (original) The composition of claim 11, wherein the second surfactant is a polyoxyethylene sorbitan fatty acid ester.

13. (original) The composition of claim 12, wherein the second surfactant is sorbitan monolaurate or Polysorbate 80.

14. (currently amended) The composition of ~~claims~~claim 1 ~~or 2~~, further comprising an organic solvent.

15. (currently amended) The composition of claim 14, wherein the organic solvent is at least one solvent selected from the group consisting of glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, tetraglycol, a medium chain length monoglyceride, [[or]]and a polyethylene glycol.

16. (original) The composition of claim 15, further comprising benzyl alcohol, α-phenethyl alcohol or β-phenethyl alcohol.

17. (previously presented) The composition of claim 3, wherein modafinil is present in the non-aqueous particle-forming composition at a concentration of about 1 to about 500 mg/ml.

18. (previously presented) The composition of claim 17, wherein modafinil is present in the non-aqueous particle-forming composition at a concentration of about 1 to about 200 mg/ml.

19. (currently amended) The composition of ~~claims~~claim 1 ~~or 2~~, wherein the non-aqueous particle-forming composition comprises a modafinil compound at a concentration of about 1 to about 100 mg/ml; a first surfactant selected from a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, a medium chain monoglyceride, a medium chain fatty acid ester, d-α-tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, and an ethoxylated hydroxystearic acid; a second surfactant selected from a polyoxyethylene sorbitan fatty acid ester; and an organic solvent selected from glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, tetraglycol, a medium chain length monoglyceride, and a polyethylene glycol.

20. (original) The composition of claim 19, wherein the modafinil compound is modafinil.

21. (original) The composition of claim 20, wherein the first surfactant is a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, or a medium chain monoglyceride; the second surfactant is a polyoxyethylene sorbitan fatty acid ester; and the organic solvent is a polyethylene glycol.

22. (original) The composition of claim 21, wherein the first surfactant is glyceryl

caprylate/caprate, glyceryl monocaprylate or polyethoxylated (40) stearic acid; the second surfactant is sorbitan monolaurate; and the organic solvent is PEG-300 or PEG-400.

23. (previously presented) The composition of claim 22, wherein the non-aqueous particle-forming composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl caprylate/caprate (w/w/w).

24. (previously presented) The composition of claim 22, wherein the non-aqueous particle-forming composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl monocaprylate (w/w/w).

25. (previously presented) The composition of claim 22, wherein the non-aqueous particle-forming composition comprises 90% PEG-400, 5% sorbitan monolaurate, 5% polyethoxylated (40) stearic acid (w/w/w).

26. (original) The composition of claim 21, wherein the first surfactant is glyceryl caprylate/caprate, glyceryl monocaprylate, polyethoxylated (40) stearic acid or a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate; the second surfactant is polyoxyethylene (80) sorbitan monooleate; and the organic solvent is PEG-300 or PEG-400.

27. (previously presented) The composition of claim 26, wherein the non-aqueous particle-forming composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl caprylate/caprate (w/w/w).

28. (previously presented) The composition of claim 26, wherein the non-aqueous particle-forming composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl monocaprylate (w/w/w).

29. (previously presented) The composition of claim 26, wherein the non-aqueous particle-forming composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan

monooleate, 15% polyethoxylated (40) stearic acid (w/w/w).

30. (previously presented) The composition of claim 26, wherein the non-aqueous particle-forming composition comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% of a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate (w/w/w).

31. (original) The composition of claim 10, wherein the composition comprises Polysorbate 80, glyceryl caprylate/caprate and a mixture of glyceryl tricaprate and glyceryl tricaprilate.

32. (currently amended) The composition of ~~claims~~claim 1 ~~or 2~~, comprising one or more unit doses of a modafinil compound.

33. (original) The composition of claim 32, comprising one unit dose of a modafinil compound.

34. (previously presented) The composition of claim 33, wherein the unit dose comprises 200 mg of a modafinil compound.

35. (previously presented) The composition of claim 33, wherein the unit dose comprises 100 mg of a modafinil compound.

36. (currently amended) A method of preparing an aqueous, liquid, homogeneous, stable composition of non-crystalline particles, ~~wherein the particles comprise a modafinil compound,~~ comprising the steps of:

(a) preparing ~~contacting~~ a non-aqueous particle-forming composition ~~of claim 1~~comprising a modafinil compound and at least one surfactant; and

(b) contacting the non-aqueous particle-forming composition with an aqueous medium to spontaneously form an aqueous, liquid, homogeneous, stable

composition of non-crystalline particles.

37. (currently amended) The method of claim 36, wherein the non-aqueous particle-forming composition ~~of claim 1~~ is contacted with an aqueous medium in vitro.

38. (currently amended) The method of claim 36, wherein the non-aqueous particle-forming composition ~~of claim 1~~ is contacted with an aqueous medium in vivo.

39. (original) The method of claim 36, wherein the modafinil compound is modafinil.

40. (currently amended) [[A]]The method of claim 36, ~~preparing an aqueous, homogeneous, stable composition of non-crystalline particles, wherein the particles comprise a modafinil compound, comprising:~~

~~(a) dissolving a modafinil compound in a liquid comprising at least one~~ wherein the surfactant or surfactants are present in an amount from about 1% to about 50%, ~~to form a non-aqueous particle forming composition of claim 1; and~~

~~(b) contacting the non-aqueous particle forming composition with an aqueous medium to form the composition of non-crystalline particles.~~

41. (previously presented) A method of treating a disease or disorder in a subject, comprising administering a therapeutically effective amount of a non-aqueous particle-forming composition of claim 1 to a subject.

42. (currently amended) A method of treating a disease or disorder in a subject, comprising:

(a) contacting [[a]]the non-aqueous particle-forming composition of claim 1 with an aqueous medium[[,]] ~~thereby~~to ~~forming~~form an aqueous, liquid, homogeneous, stable composition of non-crystalline particles, ~~wherein the particles comprise a modafinil compound~~; and

(b) administering a therapeutically effective amount of the aqueous, liquid,

homogeneous, stable composition of non-crystalline particles to a subject.

43. (currently amended) The method of ~~claims~~claim 40~~, 41 or 42~~, wherein the modafinil compound is modafinil.

44. (currently amended) The method of claim 41~~ or 42~~, wherein the composition is administered for the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive dysfunction or fatigue; or for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain to a patient in need thereof.

45. (original) The composition of claim 3, wherein upon administration of the composition to a subject in need thereof, modafinil has a blood serum level of about 0.05 to about 30 μg/ml in said subject.

46. (original) The composition of claim 45, wherein the blood serum level is from about 1 to about 20 μg/ml.

47. (previously presented) The composition of claim 1, wherein the non-aqueous particle-forming composition is suitable for oral administration to a subject.

48. (previously presented) The composition of claim 47, wherein the non-aqueous particle-forming composition is encapsulated within a capsule.

49. (original) The composition of claim 48, wherein the capsule is a soft gelatin capsule.

50. (original) The composition of claim 48, wherein the capsule is a hard capsule.

51. (currently amended) The composition of claim 2, wherein the ~~aqueous,~~

~~homogeneous, stable~~ composition is suitable for oral administration to a subject.

52. canceled.

53. canceled.

54. canceled.

55. (currently amended) The composition of ~~claims~~claim 1~~, 2, or 19~~, wherein the modafinil compound is the levorotatory form of modafinil.

56. (previously presented) The method of claim 36, wherein the modafinil compound is the levorotatory form of modafinil.

57. (currently amended) The composition of ~~claims~~claim 40~~, 41, or 42~~, wherein the modafinil compound is the levorotatory form of modafinil.

58. (currently amended) The composition of ~~claims~~claim ~~40, 41, or 42~~ wherein the modafinil compound is modafinil.

59. (new) The composition of claim 14, wherein the organic solvent has an average molecular weight of about 1500 or less.

60. (new) The method of claim 42, wherein the modafinil compound is modafinil.

61. (new) The method of claim 42, wherein the composition is administered for the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive dysfunction or fatigue; or for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain to a patient in need thereof.

62. (new) The composition of claim 2, wherein the modafinil compound is the levorotatory form of modafinil.

63. (new) The composition of claim 19, wherein the modafinil compound is the levorotatory form of modafinil.

64. (new) The composition of claim 41, wherein the modafinil compound is the levorotatory form of modafinil.

65. (new) The composition of claim 42, wherein the modafinil compound is the levorotatory form of modafinil.